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Christoffer Bro

BRO1

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05/22/2006

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/613,219

Applicant(s)

BRO ET AL.

Examiner

Walter Schlapkohl

Art Unit

1636

*waf*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/22/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Receipt is acknowledged of the papers filed 2/22/2006 in which claim 1 was amended and claim 7 was canceled. Claims 1-6 and 8-12 are currently pending and under examination.

### *Claim Objections*

Claims 3 and 5-6 are objected to because of the following informalities: Claim 3 recites "[a] micro-organism as claimed in claim 1, wherein said enzyme is encode by PGM2" in lines 1-2 and should instead recite "[a] micro-organism as claimed in claim 1, wherein said enzyme is encoded by PGM2."

Claims 1 and 5-6 recite "the said enzyme" and, for clarity, would better read simply as "said enzyme."

Appropriate correction is required.

### *Allowable Subject Matter*

The indicated (conditional) allowability of claims 5-6 is withdrawn in view of the newly discovered reference(s) to Weinstock et al (US Patent No. 6,747,137). Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4 and 9-11, and therefore dependent claims 2-3, 5-6, 8 and 12, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is new rejection not necessitated by Applicant's amendment.**

Claim 1 recites "[a] recombinant, prototrophic micro-organism exhibiting an increased level of galactose uptake rate when cultured on a nutrient source providing galactose, said micro-organism being a yeast or other fungi having the ability to grow on minimal medium and over expressing the activity of an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference micro-organism having a native level of activity of said enzyme and from which the recombinant microorganism is derived..." in lines 1-10. Claim 1 is vague and indefinite in that it is unclear what is meant by "over

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expressing the activity" of the recited enzyme. Does Applicant intend that the micro-organism overexpresses an active form of the enzyme or does Applicant intend only that the micro-organism display increased enzymatic activity or both? It is unclear whether said enzyme need be overexpressed for increased activity or whether the activity of the of said enzyme need only be increased.

Similarly, claim 4 recites "[a] micro-organism as claimed in claim 1, wherein said enzyme activity is expressed in the micro-organism at a level which is 1.5 or more times that of said reference micro-organism" in lines 1-4. Claim 4 is vague and indefinite in that it is unclear whether it is the activity of the enzyme or whether it is the expression level of the enzyme which is at least 1.5 times or more that of said reference micro-organism.

Claims 9 recites "[a] micro-organism as claimed in claim 1, which exhibits an increase of maximum specific galactose uptake rate of at least 10% in comparison to a said reference micro-organism" in lines 1-3. Claim 9 is vague and indefinite in that it is unclear whether Applicant intends an increase in the rate (i.e. speed) of galactose uptake or in the level of galactose uptake. Claim 9 is also vague and indefinite in that the term "specific galactose uptake rate" is not defined. What are the

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metes and bounds of "specific galactose uptake rate"? Does the term "specific galactose uptake rate" refer to measurements of galactose uptake rate that are performed under certain conditions or in the context of certain criteria or does the term apply to any measurement which compares galactose rates in a recombinant microorganism as recited and a wild type organism from which the recombinant microorganism is derived? Claim 9 is also vague and indefinite in that "a said reference micro-organism" could be referring to the microorganism of claim 1 or the phrase could be referring to the microorganism of claim 1 and, e.g., others of a similar nature.

Similarly, claim 10 recites, "[a] micro-organism as claimed in claim 1, which exhibits an increase of said enzyme activity of at least 2 fold in comparison to a said reference micro-organism" in lines 1-3. Does Applicant intend to refer to "said reference micro-organism" or are other reference microorganisms encompassed by the claim?

Claim 11 recites "[a] micro-organism as claimed in claim 1, which exhibits an increased maximum specific ethanol production rate compared to said reference micro-organism" in lines 1-3. Claim 11 is vague and indefinite in that it is unclear what is meant by the term "specific ethanol production rate." The term "specific ethanol production rate" does not appear to be defined

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in the instant specification. Does the phrase "specific ethanol production rate" encompass ethanol production as measured in a particular way, e.g. in g ethanol/g DW/h, as compared to the same measurement in said reference micro-organism or will any measurement of ethanol production suffice?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection not necessitated by Applicant's amendment.**

Note: for purposes of this rejection only, Examiner has interpreted the claims to be drawn to any recombinant prototrophic fungus exhibiting an increased level of galactose uptake when cultured on a nutrient source containing galactose

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and having the ability to grow on minimal medium and wherein the microorganism overexpresses an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference microorganism having a native level of activity of said enzyme and from which the recombinant microorganism is derived, and further wherein said overexpression of said enzyme (1) is due to said microorganism having multiple copies of a gene coding for said enzyme and/or (2) is due to a gene coding for said enzyme being under the control of a genetic control sequence which has been recombinantly introduced and which is not natively associated with said gene. Examiner has also interpreted the claims to encompass such a microorganism wherein the microorganism exhibits an increase in ethanol production as compared to said reference microorganism.

The claims do not provide any structural information with regard to the enzymatic sequences capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate such that the fungus exhibits an increased level of galactose uptake. Nor do the claims provide any information with regard to which species of fungi or which structural, genetic or phenotypic requirements must be met by the fungus to result in an increase in galactose uptake upon recombinant expression of an enzyme



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capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate. Thus, the rejected claims comprise a set of enzyme sequences used in conjunction with a set of fungi that are defined by their respective functions.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of a complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, and any combination thereof. The specification notes that the enzyme "may be encoded by PGM1 and PGM2" (page 5, lines 26-27). The specification also states that the enzyme of the microorganism may be a "mutated form of the said enzyme which mutated form has a higher specific activity than the native form of the said enzyme of said micro-organism" (page 6, lines 2-5) and lists several preferred micro-organisms suitable for practice of the invention including *Saccharomyces cerevisiae*, *Pichia pastoris* and *Aspergillus niger* (page 6, lines 8-21). As examples, the specification provides one prototrophic *S. cerevisiae* strain, CEN.PK113-7D, transformed with the high copy vector pPGM2 containing PGM2 (an enzyme that catalyzes the reaction of glucose-1 phosphate to glucose-6 phosphate) behind

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the PMA1 gene promoter and URA3. This strain shows increased galactose uptake and increase ethanol production as compared to the wild type strain (see Example 6 on pages 14-15).

Even if one accepts that the examples described in the specification meet the claim limitations of the rejected claims with regard to structure and function, the examples are only representative of one type of yeast transformed with one wild type enzyme capable of increasing galactose uptake and/or ethanol production. The results are not necessarily predictive of any other enzyme, wild type or mutant, capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in any other yeast or fungal strain. Thus it is impossible to extrapolate from the example described herein those enzymes and those fungi that would necessarily meet the structural/functional characteristics of the rejected claims.

The prior art does not appear to offset the deficiencies of the instant specification in that it does not describe a set of genes or proteins that when expressed in a recombinant prototrophic fungal cell, increase the amount of galactose uptake and ethanol production. Weinstock et al (US Patent No. 6,747,137) describe a fungus transformed with PGM2, but they do not disclose which fungi can be transformed with which glucose-1 phosphate → glucose-6 phosphate converting enzymes such that

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galactose uptake is increased or such that both galactose uptake and ethanol production are increased.

Given the very large genus of enzymes and microorganisms encompassed by the rejected claims, and given the limited description provided by the prior art and specification with regard to the microorganisms transformed with recombinant nucleic acids for enzymes such that enzyme activity of an enzyme catalyzing the reaction of glucose-1 phosphate to glucose-6 phosphate is increased and an increase in galactose uptake is exhibited, the skilled artisan would not have been able to describe the broadly claimed genus of recombinant prototrophic fungi exhibiting an increased level of galactose uptake when cultured on a nutrient source providing galactose and having the ability to grow on minimal medium and wherein the microorganism overexpresses an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference microorganism having a native level of activity of said enzyme and from which the recombinant microorganism is derived, and further wherein said overexpression of said enzyme (1) is due to said microorganism having multiple copies of a gene coding for said enzyme and/or (2) is due to a gene coding for said enzyme being under the control of a genetic control sequence which has been

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recombinantly introduced and which is not natively associated with said gene. Nor would the artisan of ordinary skill in the art have been able to describe the broadly claimed genus of such microorganisms wherein the microorganisms exhibit an increase in ethanol production as compared to a reference microorganism. Thus, there is no structural/functional basis provided by the prior art or instant specification for one of skill in the art to envision those enzymes, either alone or in combination with suitable fungal hosts, that satisfy the functional limitations of the claims. Therefore, the skilled artisan would have reasonably concluded applicants were not in possession of the claimed invention for claims 1-6 and 8-12.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for wild type *PGM2* in *S. cerevisiae*, does not reasonably provide enablement for a recombinant, prototrophic fungus comprising any enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway. Nor does the specification reasonably provide enablement for the use of such any such enzyme, or even any phosphoglucomutase, in any yeast or fungus. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. **This is a new rejection not necessitated by Applicant's amendment.**

Note: for purposes of this rejection only, Examiner has interpreted the claims to be drawn to any recombinant prototrophic fungus exhibiting an increased level of galactose uptake when cultured on a nutrient source providing galactose and having the ability to grow on minimal medium and wherein the microorganism overexpresses an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference microorganism having a native level of activity of said enzyme and from which the recombinant microorganism is derived, and further wherein said overexpression of said enzyme (1) is due to said microorganism having multiple copies of a gene coding for said enzyme and/or (2) is due to a gene coding for said enzyme being under the control of a genetic control sequence which has been recombinantly introduced and which is not natively associated with said gene. Examiner has also interpreted the claims to encompass such a microorganism wherein the microorganism exhibits an increase in ethanol production as compared to said reference microorganism.

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Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). These include: nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the quantity of experimentation necessary, the relative skill levels of those in the art, and the breadth of the claims. The most relevant *Wands* factors for evaluating the enablement of the instant rejection are discussed below.

*Nature of the invention and Breadth of the Claims:* The nature of the invention is complex and the breadth of the claims is wide. The invention is drawn to any recombinant prototrophic fungus having the ability to grow on minimal medium and over-expressing the activity of an enzyme catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference microorganism having a native level of activity of said enzyme and from which the recombinant microorganism is derived, wherein said overexpression of said enzyme (1) is due to said microorganism having multiple copies of a gene coding for said enzyme and/or (2) is due to a gene coding for said enzyme being under the control of a genetic control sequence which has been recombinantly introduced and which is not natively associated

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with said gene. Some claims are further limited to such a microorganism which is a yeast and which expresses a phosphoglucomutase. Other claims are further limited to such a microorganism wherein the microorganism exhibits an increase in ethanol production. The invention encompasses any enzyme capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate. The invention also encompasses any recombinant prototrophic fungus. The large number of enzymes and fungi encompassed by the claims exacerbates the complex nature of the invention.

*State of the Art:* At the time of filing, at least four enzymes, (N-acetylglucosamine-phosphate mutase (AGM), phosphoglucomutases 1 and 2 (PGM1 and PGM2) and phosphomannomutase (PMM), were known to catalyze the conversion of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway (Hofmann et al, *European Journal of Biochemistry* **221**: 741-747, 1994, see entire document, especially Figure 4). Hofmann et al conclude that with regard to the various enzymes capable of converting glucose-1 phosphate to glucose-6 phosphate, "there are different hexosephosphate mutases in yeast which have partially overlapping substrate specificities but distinct physiological functions" (page 746, last paragraph). It is further noted, that at the time of

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filing genes encoding phosphoglucomutases had been found in organisms ranging from bacteria to mammals and that isoforms of phosphoglucomutases were known to exist in many organism (Hoffman, et al, Molecular General Genetics 262: 1001-1011, 2000; see entire document, especially page 1001, second column). Yet the art the time of Applicant's filing is silent with regard to which phosphoglucomutases are capable of being expressed in a fungus such that the overexpression of such an enzyme results in a fungus with increased galactose uptake or both increased galactose uptake and increased ethanol production.

*The Amount of Direction or Guidance Present and the Presence of Working Examples:* The instant specification discloses one example of a prototrophic recombinant fungus which overexpresses *PGM2* and which exhibits increased galactose uptake and increased ethanol production when compared to the native fungus from which it was derived. The specification does not provide any guidance with regard to which other phosphoglucomutases, much less which other enzymes capable of converting glucose-1 phosphate to glucose-6 phosphate, are capable of being overexpressed in a fungus such that galactose uptake and ethanol production are increased. Furthermore, the specification lists many different strains of yeast and fungi suitable for use in the invention (see, e.g., page 6 of the



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instant specification), but does not provide any guidance with respect to which enzymes capable of converting glucose-1 phosphate to glucose-6 phosphate are suitable for use in which fungi such that galactose uptake and ethanol production are increased.

*The Level of Unpredictability and The Amount of Experimentation Required:* Given the undeveloped level in the state of the art with regard to prototrophic recombinant fungi transformed with an enzyme capable of converting glucose-1 phosphate to glucose-6 phosphate and wherein galactose uptake and ethanol production are increased, as well as the lack of guidance provided by both the state of the art and the instant disclosure, the level of unpredictability when reducing the large genus of instantly-claimed embodiments of the invention to practice is quite high. Furthermore, the underdeveloped state of the art, the lack of guidance provided by the specification and the prior art, and the high level of unpredictability in art would require one of ordinary skill in the art to perform an inordinate amount of trial-and-error experimentation in order to determine which enzymes capable of catalyzing the conversion of glucose-1 phosphate to glucose-6 phosphate, when overexpressed in a fungus, would result in a recombinant fungus exhibiting

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increased galactose uptake, and with respect to claims 11 and 12, increased galactose uptake and increased ethanol production.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Weinstock et al (US Patent No. 6,747,137). **To the extent that this rejection is applied to claims 5-6, this is a new rejection not necessitated by Applicant's amendment.**

Note: for purposes of this rejection only, Examiner has interpreted the claims to be drawn to any recombinant prototrophic fungus exhibiting an increased level of galactose uptake when cultured on a nutrient source providing galactose and having the ability to grow on minimal medium and wherein the microorganism overexpresses an enzyme catalyzing the conversion

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of glucose-1 phosphate to glucose-6 phosphate in the galactose uptake and metabolism pathway compared to a reference microorganism having a native level of activity of said enzyme and from which the recombinant microorganism is derived, and further wherein said overexpression of said enzyme (1) is due to said microorganism having multiple copies of a gene coding for said enzyme and/or (2) is due to a gene coding for said enzyme being under the control of a genetic control sequence which has been recombinantly introduced and which is not natively associated with said gene. Examiner has also interpreted the claims to encompass such a microorganism wherein the microorganism exhibits an increase in ethanol production as compared to said reference microorganism.

Weinstock et al teach a recombinant fungal cell transformed with SEQ ID NO: 2964 which encodes Phosphoglucomutase 2 (see entire document, especially column 8, lines 6-36; column 43, lines 47-67; column 44, lines 1-36; and Table 2, column 415, SEQ ID NO: 2964). Weinstock et al teach that this transformed host can be either the native (prototrophic) host or a recombinant host (e.g., see column 8, lines 34-35) and explicitly lists *Saccharomyces cerevisiae* and *Candida putida* as strains which can be used as hosts (see, e.g., column 22, lines 15-16. Although Weinstock et al do not specifically teach that such a

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transformed fungus would exhibit increased galactose uptake when cultured on a nutrient source containing galactose and have the ability to grow on minimal media, such limitations which are found in claim 1 are still met by the Weinstock et al reference because such limitations are inherent to a prototrophic fungus which overexpresses *PGM2*. Moreover, Weinstock et al teach a *PGM-2* transformed *S. cerevisiae*, the same yeast and enzyme combination used in Applicant's instant Example 6 of the disclosure which describes Applicant's only working example of such a recombinant prototrophic fungus and which provides support for all the pending claims. Regarding claim 5, Weinstock et al teach such an organism having multiple copies of the gene/vector comprising the gene (see, e.g., column 43, lines 57-67). Regarding claim 6, Weinstock et al also teach that the gene coding for the enzyme is under the control of a genetic control sequence which has been recombinantly introduced and which is not natively associated with said gene (see, e.g., column 44, lines 16-26). Regarding claims 11-12, such a transformed fungus as taught by Weinstock et al would also inherently exhibit an increased amount of ethanol production.

#### Conclusion

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Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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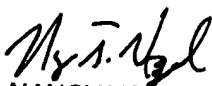
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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

May 4, 2006

  
NANCY VOGEL  
PRIMARY EXAMINER